



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

February 6, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-23

Ralph Vandyk, Owner
Vandyk Dairy
7000 West Ustick Road
Meridian, Idaho 83642

WARNING LETTER

Dear Mr. Vandyk:

An investigation at your dairy located at 7000 West Ustick Road, Meridian, Idaho 83642, by our investigator on October 30, 2000 confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On or about May 18, 2000, you sold a culled dairy cow back tag # 82 VL 0092 identified on USDA lab report # 281070 for slaughter as human food to [REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of 2.96 parts per million (PPM) of penicillin in the kidney. The allowable tolerance for penicillin in the uncooked edible tissue of cattle is 0.05 PPM.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply.

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For example, our investigator noted the following conditions on your farm:

1. You failed to review treatment records to assure that the treated cow had been held in accordance with the labeled instructions on the penicillin G procaine prior to slaughter.
2. You failed to follow the label directions by administering the penicillin G procaine in excess of the labeled directions.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Our investigation revealed that the penicillin residue came from your use of penicillin G procaine in excess of the dosage instructions on your dairy herd. The dosage instructions provided by the manufacturer of the penicillin is intended to provide you with withdrawal time information, which you are required to follow. Not following the manufacturer instructions can be considered off label use. Off label use of veterinary drugs is a deviation from Title 21, Code of Federal Regulations (21 CFR), Part 530.

In October of 1994, Congress passed the Animal Medicinal Drug Use Clarification Act, which permits extra-label use under certain controlled conditions, specified in 21 CFR Part 530. Extra label use is only permitted if the use is by or on the lawful order of a licensed veterinarian within the context of a valid veterinarian/client/patient relationship and in conformance with criteria set forth in Part 530.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson,

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Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Bruce Williamson, Compliance Officer, (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosure:
Form FDA 483

CC:
Dr. Ahmed/USDA/FSIS/Tissue Residue
Landmark Center, Suite 300
1299 Farnam St.
Omaha, Nebraska 68102